CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-318

MICROBIOLOGY REVIEW(S)

NDA 21-318
Forteo (tereparatide) Injection
Lilly Research Laboratories

Forteo is a bisphosphonate, and has no potential for abuse.

REVIEW FOR HFD-510
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #2 OF NDA 21-318
22 August 2001

A. 1. NDA 21-318

APPLICANT: Lilly Research Laboratories
Lilly Corporate Center
Indianapolis, IN 46285

2. PRODUCT NAMES: Forteo® (teriparatide injection)

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is an injectable for subcutaneous injection. The product is packaged in a 3-mL cartridge, containing 250 µg/mL of rhPTH (1-34).

4. METHODS OF STERILIZATION:
The drug product is aseptically filled.

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:

B. 1. DATE OF INITIAL SUBMISSION: 29 November 2000

2. DATE OF AMENDMENT: 15 March 2001 (Subject of this Review)

3. RELATED DOCUMENTS:

4. ASSIGNED FOR REVIEW: 22 August 2001

C. REMARKS: The product is to be manufactured at:

Eli Lilly France S.A.
rue du Colonel Lilly
67640 Fegersheim, France.

D. CONCLUSIONS: The application is recommended for approval on the basis of sterility assurance.

Paul Stinavage, Ph.D.

cc: Original NDA 21-318
HFD-805/Stinavage/Consult File
HFD-510/Div File/R. Hedin/Y. Yang

Drafted by: P. Stinavage, 22 August 2001
R/D initialed by P. Cooney

APPEARS THIS WAY
ON ORIGINAL

THIS SECTION WAS DETERMINED **NOT** TO BE RELEASABLE

1 page

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/s/

Paul Stinavage
8/23/01 01:49:41 PM
MICROBIOLOGIST
Response to deficiencies.

Peter Cooney
8/23/01 02:12:23 PM
MICROBIOLOGIST

APPEARS THIS WAY
ON ORIGINAL

REVIEW FOR HFD-510
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1 OF NDA 21-318
1 February 2001

A. 1. NDA 21-318

APPLICANT: Lilly Research Laboratories
Lilly Corporate Center
Indianapolis, IN 46285

2. PRODUCT NAMES: Forteo® (teriparatide injection)

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is an injectable for subcutaneous injection. The product is packaged in a 3-mL cartridge, containing 250 µg/mL of rhPTH (1-34).

4. METHODS OF STERILIZATION:
The drug product is aseptically filled.

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:

B. 1. DATE OF INITIAL SUBMISSION: 29 November 2000

2. DATE OF AMENDMENT: (none)

3. RELATED DOCUMENTS:

4. ASSIGNED FOR REVIEW: 21 December 2000

C. REMARKS: The product is to be manufactured at:

Eli Lilly France S.A.
rue du Colonel Lilly
67640 Fegersheim, France.

D. CONCLUSIONS: The application is approvable pending resolution of microbiology concerns. Specific comments are provided in "E. Review Notes" and "List of Microbiology Deficiencies".

Paul Stinavage, Ph.D.

cc: Original NDA 21-318
HFD-805/Stinavage/Consult File
HFD-510/Div File/R. Hedin/Y. Yang

Drafted by: P. Stinavage, 1 February 2001
R/D initialed by P. Cooney

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10 pages

/s/

Paul Stinavage
2/22/01 05:07:00 AM
MICROBIOLOGIST
New NDA product manufacture at Fegersheim, France.

Peter Cooney
2/22/01 09:50:48 AM
MICROBIOLOGIST